



## Clinical trial results:

### A Phase 2b Multicenter, Randomized, Placebo-controlled, Dose-ranging Study to Evaluate the Efficacy and Safety of JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2021-003700-41   |
| Trial protocol           | ES               |
| Global end of trial date | 16 December 2022 |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 30 December 2023 |
| First version publication date | 30 December 2023 |

#### Trial information

##### Trial identification

|                       |                 |
|-----------------------|-----------------|
| Sponsor protocol code | 77242113PSO2001 |
|-----------------------|-----------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT05223868 |
| WHO universal trial number (UTN)   | -           |

Notes:

##### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Janssen Research & Development, LLC  |
| Sponsor organisation address | 920 Route 202, South Raritan, New Jersey, United States, 08869                             |
| Public contact               | Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |
| Scientific contact           | Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |

Notes:

##### Paediatric regulatory details

|  |    |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 20 January 2023  |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 16 December 2022 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the dose response of JNJ-77242113 at Week 16 in subjects with moderate-to-severe plaque psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 03 February 2022 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                        |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Canada: 35             |
| Country: Number of subjects enrolled | Germany: 47            |
| Country: Number of subjects enrolled | Spain: 9               |
| Country: Number of subjects enrolled | France: 7              |
| Country: Number of subjects enrolled | United Kingdom: 3      |
| Country: Number of subjects enrolled | Japan: 20              |
| Country: Number of subjects enrolled | Korea, Republic of: 11 |
| Country: Number of subjects enrolled | Poland: 60             |
| Country: Number of subjects enrolled | Taiwan: 13             |
| Country: Number of subjects enrolled | United States: 50      |
| Worldwide total number of subjects   | 255                    |
| EEA total number of subjects         | 123                    |

Notes:

### Subjects enrolled per age group

|   |   |
|---|---|
| In utero                                  | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |

|  |     |
|--|-----|
| Newborns (0-27 days)                     | 0   |
| Infants and toddlers (28 days-23 months) | 0   |
| Children (2-11 years)                    | 0   |
| Adolescents (12-17 years)                | 0   |
| Adults (18-64 years)                     | 236 |
| From 65 to 84 years                      | 19  |
| 85 years and over                        | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 255 subjects were randomised and treated in the study. After Week 16 subjects who were not enrolled in long term extension (LTE) study (NCT05364554) were followed up for safety up to 4 weeks after the last dose of the study drug.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Randomised - controlled        |
| Blinding used                | Double blind                   |
| Roles blinded                | Subject, Investigator          |

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | Placebo |

Arm description:

Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.

|  |                    |
|--|--------------------|
| Arm type                               | Placebo            |
| Investigational medicinal product name | Placebo            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Subjects received placebo tablets, 2 in the morning and 1 in the evening daily.

|                  |                                 |
|------------------|---------------------------------|
| <b>Arm title</b> | JNJ-77242113 25 mg QD + Placebo |
|------------------|---------------------------------|

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Placebo            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Subjects received 1 placebo tablet in the morning and 1 in the evening.

|  |                    |
|--|--------------------|
| Investigational medicinal product name | JNJ-77242113       |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Subjects received JNJ-77242113 25 mg tablet once daily.

|                  |                                 |
|------------------|---------------------------------|
| <b>Arm title</b> | JNJ-77242113 50 mg QD + Placebo |
|------------------|---------------------------------|

**Arm description:**

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2\*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Placebo            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Subjects received 1 placebo tablet in the evening.

|  |                    |
|--|--------------------|
| Investigational medicinal product name | JNJ-77242113       |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Subjects received JNJ-77242113 25 mg 2 tablets once daily.

|                  |                                  |
|------------------|----------------------------------|
| <b>Arm title</b> | JNJ-77242113 25 mg BID + Placebo |
|------------------|----------------------------------|

**Arm description:**

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Placebo            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Subjects received placebo tablet in the morning.

|  |                    |
|--|--------------------|
| Investigational medicinal product name | JNJ-77242113       |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Subjects received JNJ-77242113 25 mg tablet twice daily.

|                  |                                  |
|------------------|----------------------------------|
| <b>Arm title</b> | JNJ-77242113 100 mg QD + Placebo |
|------------------|----------------------------------|

**Arm description:**

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | JNJ-77242113       |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Subjects received JNJ-77242113 100 mg tablet once daily.

|  |                    |
|--|--------------------|
| Investigational medicinal product name | Placebo            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Subjects received 1 placebo tablet in the morning and 1 in the evening.

|                  |                                   |
|------------------|-----------------------------------|
| <b>Arm title</b> | JNJ-77242113 100 mg BID + Placebo |
|------------------|-----------------------------------|

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Placebo            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Subjects received placebo tablet in the morning.

|  |                    |
|--|--------------------|
| Investigational medicinal product name | JNJ-77242113       |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Subjects received JNJ-77242113 100 mg tablet twice daily.

| <b>Number of subjects in period 1</b> | Placebo | JNJ-77242113 25 mg QD + Placebo | JNJ-77242113 50 mg QD + Placebo |
|---------------------------------------|---------|---------------------------------|---------------------------------|
| Started                               | 43      | 43                              | 43                              |
| Completed                             | 36      | 36                              | 40                              |
| Not completed                         | 7       | 7                               | 3                               |
| Unspecified                           | -       | 2                               | -                               |
| Lost to follow-up                     | 1       | 3                               | -                               |
| Withdrawal by subject                 | 6       | 2                               | 3                               |

| <b>Number of subjects in period 1</b> | JNJ-77242113 25 mg BID + Placebo | JNJ-77242113 100 mg QD + Placebo | JNJ-77242113 100 mg BID + Placebo |
|---------------------------------------|----------------------------------|----------------------------------|-----------------------------------|
| Started                               | 41                               | 43                               | 42                                |

|                       |    |    |    |
|-----------------------|----|----|----|
| Completed             | 40 | 41 | 38 |
| Not completed         | 1  | 2  | 4  |
| Unspecified           | -  | 1  | 1  |
| Lost to follow-up     | -  | -  | 1  |
| Withdrawal by subject | 1  | 1  | 2  |

## Baseline characteristics

### Reporting groups

|  |                                   |
|--|-----------------------------------|
| Reporting group title  | Placebo                           |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.                  |                                   |
| Reporting group title  | JNJ-77242113 25 mg QD + Placebo   |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug. |                                   |
| Reporting group title  | JNJ-77242113 50 mg QD + Placebo   |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                              |                                   |
| Reporting group title  | JNJ-77242113 25 mg BID + Placebo  |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                    |                                   |
| Reporting group title  | JNJ-77242113 100 mg QD + Placebo  |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                          |                                   |
| Reporting group title  | JNJ-77242113 100 mg BID + Placebo |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                                     |                                   |

| Reporting group values                      | Placebo | JNJ-77242113 25 mg QD + Placebo | JNJ-77242113 50 mg QD + Placebo |
|---|---------|---------------------------------|---------------------------------|
| Number of subjects                          | 43      | 43                              | 43                              |
| Title for AgeCategorical<br>Units: subjects |         |                                 |                                 |
| Children (2-11 years)                       | 0       | 0                               | 0                               |
| Adolescents (12-17 years)                   | 0       | 0                               | 0                               |
| Adults (18-64 years)                        | 38      | 42                              | 40                              |
| From 65 to 84 years                         | 5       | 1                               | 3                               |
| 85 years and over                           | 0       | 0                               | 0                               |
| Title for AgeContinuous<br>Units: years     |         |                                 |                                 |
| arithmetic mean                             | 43.9    | 44.5                            | 45.1                            |
| standard deviation                          | ± 14.7  | ± 12.72                         | ± 11.08                         |



|                  |    |    |    |
|------------------|----|----|----|
| Title for Gender |    |    |    |
| Units: subjects  |    |    |    |
| Female           | 18 | 11 | 16 |
| Male             | 25 | 32 | 27 |

| Reporting group values    | JNJ-77242113 25 mg BID + Placebo | JNJ-77242113 100 mg QD + Placebo | JNJ-77242113 100 mg BID + Placebo |
|---------------------------|----------------------------------|----------------------------------|-----------------------------------|
| Number of subjects        | 41                               | 43                               | 42                                |
| Title for AgeCategorical  |                                  |                                  |                                   |
| Units: subjects           |                                  |                                  |                                   |
| Children (2-11 years)     | 0                                | 0                                | 0                                 |
| Adolescents (12-17 years) | 0                                | 0                                | 0                                 |
| Adults (18-64 years)      | 37                               | 39                               | 40                                |
| From 65 to 84 years       | 4                                | 4                                | 2                                 |
| 85 years and over         | 0                                | 0                                | 0                                 |
| Title for AgeContinuous   |                                  |                                  |                                   |
| Units: years              |                                  |                                  |                                   |
| arithmetic mean           | 45.7                             | 44.7                             | 42                                |
| standard deviation        | ± 11.91                          | ± 14.11                          | ± 11.34                           |
| Title for Gender          |                                  |                                  |                                   |
| Units: subjects           |                                  |                                  |                                   |
| Female                    | 11                               | 11                               | 12                                |
| Male                      | 30                               | 32                               | 30                                |

| Reporting group values    | Total |  |  |
|---------------------------|-------|--|--|
| Number of subjects        | 255   |  |  |
| Title for AgeCategorical  |       |  |  |
| Units: subjects           |       |  |  |
| Children (2-11 years)     | 0     |  |  |
| Adolescents (12-17 years) | 0     |  |  |
| Adults (18-64 years)      | 236   |  |  |
| From 65 to 84 years       | 19    |  |  |
| 85 years and over         | 0     |  |  |
| Title for AgeContinuous   |       |  |  |
| Units: years              |       |  |  |
| arithmetic mean           |       |  |  |
| standard deviation        | -     |  |  |
| Title for Gender          |       |  |  |
| Units: subjects           |       |  |  |
| Female                    | 79    |  |  |
| Male                      | 176   |  |  |

## End points

### End points reporting groups

|  |                                   |
|--|-----------------------------------|
| Reporting group title  | Placebo                           |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.                  |                                   |
| Reporting group title  | JNJ-77242113 25 mg QD + Placebo   |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug. |                                   |
| Reporting group title  | JNJ-77242113 50 mg QD + Placebo   |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                              |                                   |
| Reporting group title  | JNJ-77242113 25 mg BID + Placebo  |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                    |                                   |
| Reporting group title  | JNJ-77242113 100 mg QD + Placebo  |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                          |                                   |
| Reporting group title  | JNJ-77242113 100 mg BID + Placebo |
| Reporting group description:<br>Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.                                     |                                   |

### Primary: Percentage of Subjects Who Achieved at Least 75 Percent (%) Improvement From Baseline in Psoriasis Area and Severity Index (PASI-75) at Week 16

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved at Least 75 Percent (%) Improvement From Baseline in Psoriasis Area and Severity Index (PASI-75) at Week 16 <sup>[1]</sup> |
|-----------------|--|

#### End point description:

Percentage of subjects who achieved PASI-75 score (greater than or equal to [ $\geq$ ] 75 percent [%] improvement from baseline in PASI) at Week 16 were reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. Full analysis set (FAS) included all randomised subjects who received at least 1 administration of study intervention.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline, Week 16

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be analyzed for this endpoint.

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 9.3             | 37.2                                  | 58.1                                  | 51.2                                   |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |
| number (not applicable)       | 65.1                                   | 78.6                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in PASI Total Score at Week 16

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in PASI Total Score at Week 16 |
|-----------------|---|

End point description:

Change from baseline in PASI total score at Week 16 was reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) referred to the number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values                     | Placebo            | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|--------------------------------------|--------------------|---------------------------------------|---------------------------------------|--|
| Subject group type                   | Reporting group    | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed          | 40                 | 37                                    | 41                                    | 40                                     |
| Units: Units on a scale              |                    |                                       |                                       |  |
| arithmetic mean (standard deviation) | -3.59 (±<br>9.436) | -12.76 (±<br>8.050)                   | -14.56 (±<br>6.528)                   | -12.73 (±<br>8.021)                    |

| End point values                     | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|--------------------------------------|--|---|--|--|
| Subject group type                   | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed          | 42                                     | 39                                      |  |  |
| Units: Units on a scale              |  |   |  |  |
| arithmetic mean (standard deviation) | -13.99 (±<br>8.653)                    | -17.44 (±<br>8.356)                     |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved at Least 90% Improvement From Baseline in PASI (PASI-90) at Week 16

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects Who Achieved at Least 90% Improvement From Baseline in PASI (PASI-90) at Week 16 |
|-----------------|---|

End point description:

Percentage of subjects who achieved PASI-90 score ( $\geq 90\%$  improvement from baseline in PASI) at Week 16 were reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. FAS included all randomised subjects who received at least 1 administration of study intervention.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 2.3             | 25.6                                  | 51.2                                  | 26.8                                   |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |
| number (not applicable)       | 46.5                                   | 59.5                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved at Least 100% Improvement From Baseline in PASI (PASI-100) at Week 16

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects Who Achieved at Least 100% Improvement From Baseline in PASI (PASI-100) at Week 16 |
|-----------------|---|

End point description:

Percentage of subjects who achieved PASI-100 score ( $\geq 100\%$  improvement from baseline in PASI) at Week 16 were reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas was assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. FAS included all randomised subjects who received at least 1 administration of study intervention.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 0               | 11.6                                  | 25.6                                  | 9.8                                    |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |

|                         |      |      |  |  |
|-------------------------|------|------|--|--|
| number (not applicable) | 23.3 | 40.5 |  |  |
|-------------------------|------|------|--|--|

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved an Investigator Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved an Investigator Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16 |
|-----------------|--|

End point description:

Percentage of subjects who achieved an IGA score of cleared (0) or minimal (1) at Week 16 was reported. The IGA documented the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions were graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 11.6            | 39.5                                  | 58.1                                  | 51.2                                   |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |
| number (not applicable)       | 62.8                                   | 64.3                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) at Week 16**

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved an IGA Score of Cleared (0) at Week 16 |
|-----------------|--|

End point description:

Percentage of subjects who achieved an IGA score of cleared (0) at Week 16 was reported. The IGA documented the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions were graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 0               | 16.3                                  | 34.9                                  | 14.6                                   |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |
| number (not applicable)       | 27.9                                   | 45.2                                    |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Percent Change From Baseline in Body Surface Area (BSA) at Week 16**

|                 |  |
|-----------------|--|
| End point title | Percent Change From Baseline in Body Surface Area (BSA) at Week 16 |
|-----------------|--|

End point description:

BSA was commonly used measure of severity of skin disease. It was defined as the percentage of surface area of the body involved with the condition being assessed, (that is, plaque psoriasis). BSA was assessed using hand print method where the surface area of the subject's hand including the palm and all 5 digits was used as a guide to estimate 1% BSA. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values                     | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|--------------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type                   | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed          | 40              | 37                                    | 41                                    | 40                                     |
| Units: Percent change                |                 |                                       |                                       |  |
| arithmetic mean (standard deviation) | -2.4 (± 16.51)  | -11.9 (± 10.00)                       | -15.3 (± 11.41)                       | -13.3 (± 11.08)                        |

| End point values                     | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|--------------------------------------|--|---|--|--|
| Subject group type                   | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed          | 42                                     | 39                                      |  |  |
| Units: Percent change                |  |   |  |  |
| arithmetic mean (standard deviation) | -14.6 (± 14.03)                        | -21.0 (± 13.74)                         |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in PSSD Signs Score at Week 16

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in PSSD Signs Score at Week 16 |
|-----------------|---|

End point description:

Change from baseline in PSSD sign scores at Week 16 was reported. PSSD was a PRO questionnaire designed to measure severity of psoriasis symptoms and signs for assessment of treatment benefit. PSSD was a self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. The severity of each item was rated on 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (least severe sign) to 100 (most severe sign) were derived. Higher score indicated more severe disease. FAS: all randomised subjects who received at least 1 administration of study intervention. 'N' (number of subjects analysed): number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16



| End point values                     | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|--------------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type                   | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed          | 40              | 37                                    | 41                                    | 40                                     |
| Units: Units on a scale              |                 |                                       |                                       |  |
| arithmetic mean (standard deviation) | -6.2 (± 22.38)  | -38.6 (± 27.55)                       | -42.7 (± 28.70)                       | -41.8 (± 27.78)                        |

| End point values                     | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|--------------------------------------|--|---|--|--|
| Subject group type                   | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed          | 42                                     | 39                                      |  |  |
| Units: Units on a scale              |  |   |  |  |
| arithmetic mean (standard deviation) | -41.9 (± 28.65)                        | -51.1 (± 26.01)                         |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores at Week 16

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores at Week 16 |
|-----------------|--|

End point description:

Change from baseline in PSSD symptoms scores at Week 16 was reported. PSSD was a patient-reported outcome (PRO) questionnaire designed to measure severity of psoriasis symptoms and signs for the assessment of treatment benefit. PSSD was self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. Severity of each item was rated on 11-point numeric scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (least severe symptom) to 100 (most severe symptom) were derived. Higher score indicated more severe disease. FAS: all randomised subjects who received at least 1 administration of study intervention. 'N' (number of subjects analysed): number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values                     | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|--------------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type                   | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed          | 40              | 37                                    | 41                                    | 40                                     |
| Units: Units on a scale              |                 |                                       |                                       |  |
| arithmetic mean (standard deviation) | -0.8 (± 29.59)  | -35.8 (± 29.22)                       | -36.7 (± 29.95)                       | -34.0 (± 29.19)                        |

| End point values                     | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|--------------------------------------|--|---|--|--|
| Subject group type                   | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed          | 42                                     | 39                                      |  |  |
| Units: Units on a scale              |  |   |  |  |
| arithmetic mean (standard deviation) | -29.4 (±<br>28.28)                     | -44.0 (±<br>31.22)                      |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved PSSD Sign Score = 0 at Week 16 Among Subjects With a Baseline Sign Score ≥1

|   |   |
|---|---|
| End point title   | Percentage of Subjects Who Achieved PSSD Sign Score = 0 at Week 16 Among Subjects With a Baseline Sign Score ≥1 |
| End point description:  |   |
| <p>The PSSD was a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs for the assessment of treatment benefit. PSSD was a self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. The severity of each item was rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (indicated least severe sign) to 100 (indicated most severe sign) were derived. A higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention.</p> |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Baseline, Week 16   |   |

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 0               | 2.3                                   | 14.0                                  | 9.8                                    |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |

|                         |      |      |  |  |
|-------------------------|------|------|--|--|
| number (not applicable) | 16.3 | 14.3 |  |  |
|-------------------------|------|------|--|--|

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Achieved PSSD Symptoms Score Equal to (=) 0 at Week 16 Among Subjects With a Baseline Symptoms Score Greater Than or Equal to (>=) 1

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects Who Achieved PSSD Symptoms Score Equal to (=) 0 at Week 16 Among Subjects With a Baseline Symptoms Score Greater Than or Equal to (>=) 1 |
|-----------------|---|

End point description:

The PSSD was a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs for the assessment of treatment benefit. PSSD was a self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. The severity of each item was rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (indicated least severe symptom) to 100 (indicated most severe symptom) were derived. A higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 42                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 0               | 16.3                                  | 23.8                                  | 17.1                                   |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 42                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |
| number (not applicable)       | 27.9                                   | 26.2                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Achieved a Dermatological Life Quality Index (DLQI) of 0 or 1 at Week 16 Among Subjects With Baseline DLQI Score Greater Than (>) 1

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved a Dermatological Life Quality Index (DLQI) of 0 or 1 at Week 16 Among Subjects With Baseline DLQI Score Greater Than (>) 1 |
|-----------------|--|

End point description:

The DLQI was a dermatology specific health-related quality of life (HRQoL) instrument designed to assess the impact of the disease on a subject's HRQoL. It was a 10-item questionnaire that assesses HRQoL over the past week and in addition to evaluating overall HRQoL, could be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Each question was scored on a 4-point scale of 0 to 3 (0 = not at all, 1 = a little; 2 = a lot; or 3 = very much, where higher score indicated more impact on QoL). The total score was sum of scores from all 10 questions and it ranged from 0 (not at all) to 30 (very much), with a higher score indicating greater impact on HRQoL. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) referred to the number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 41              | 43                                    | 43                                    | 40                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       | 2.4             | 27.9                                  | 37.2                                  | 30.0                                   |

| End point values              | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|-------------------------------|--|---|--|--|
| Subject group type            | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed   | 43                                     | 41                                      |  |  |
| Units: Percentage of subjects |  |   |  |  |
| number (not applicable)       | 55.8                                   | 43.9                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Domain Scores of the Patient-Reported Outcomes Measurement Information System (PROMIS-29) at Week 16

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Domain Scores of the Patient-Reported Outcomes Measurement Information System |
|-----------------|---|

## End point description:

The PROMIS-29, a 29-item generic HRQoL survey, assesses each 7 PROMIS domains (depression; anxiety; physical function; pain interference; fatigue; sleep disturbance and ability to participate in social roles and activities) with 4 questions. The questions were ranked on 5-point Likert Scale (1=never, 2=rarely, 3=sometimes, 4=often and 5= always). Pain intensity was rated on 11-point scale (0=no pain; 10=worst imaginable pain). Norm-based scores have been calculated for each domain on PROMIS measures, score of 50 represents mean or average of reference population. Score of 60 means that person is one standard deviation above reference population. On symptom-oriented domains (anxiety, depression, fatigue, pain interference and sleep disturbance), higher scores represent worse symptomatology. On function-oriented domains (physical functioning and social role), higher scores represent better functioning. FAS was analysed. 'N'= number of subjects evaluable for this endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values                     | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|--------------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type                   | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed          | 40              | 37                                    | 41                                    | 40                                     |
| Units: Units on a scale              |                 |                                       |                                       |  |
| arithmetic mean (standard deviation) |                 |                                       |                                       |  |
| Physical Function                    | -1.04 (± 5.929) | 2.30 (± 6.060)                        | 5.81 (± 6.896)                        | 4.55 (± 7.789)                         |
| Anxiety                              | -2.36 (± 7.971) | -3.98 (± 8.789)                       | -5.27 (± 8.026)                       | -5.27 (± 6.787)                        |
| Depression                           | -1.01 (± 6.238) | -3.09 (± 8.709)                       | -3.23 (± 6.576)                       | -1.96 (± 6.569)                        |
| Fatigue                              | -0.76 (± 5.469) | -2.44 (± 10.983)                      | -1.50 (± 7.801)                       | -3.09 (± 8.676)                        |
| Sleep Disturbance                    | 0.14 (± 6.099)  | -1.89 (± 5.859)                       | -3.45 (± 7.947)                       | -4.36 (± 6.041)                        |
| Social Roles and Activities          | 0.99 (± 8.393)  | 4.31 (± 9.035)                        | 4.82 (± 8.511)                        | 5.39 (± 10.908)                        |
| Pain Interference                    | 0.09 (± 7.819)  | -6.79 (± 9.038)                       | -7.41 (± 9.867)                       | -7.18 (± 7.956)                        |
| Pain Intensity                       | 0.7 (± 2.89)    | -2.6 (± 2.94)                         | -2.7 (± 3.25)                         | -2.6 (± 3.25)                          |

| End point values                     | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|--------------------------------------|--|---|--|--|
| Subject group type                   | Reporting group                        | Reporting group                         |  |  |
| Number of subjects analysed          | 42                                     | 39                                      |  |  |
| Units: Units on a scale              |  |   |  |  |
| arithmetic mean (standard deviation) |  |   |  |  |
| Physical Function                    | 3.10 (± 7.325)                         | 5.81 (± 8.408)                          |  |  |
| Anxiety                              | -4.70 (± 8.570)                        | -8.31 (± 9.693)                         |  |  |
| Depression                           | -2.62 (± 7.465)                        | -3.67 (± 8.912)                         |  |  |
| Fatigue                              | -2.98 (± 7.818)                        | -3.75 (± 8.409)                         |  |  |

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Sleep Disturbance           | -1.04 (± 5.995) | -3.19 (± 5.705) |  |  |
| Social Roles and Activities | 5.78 (± 7.538)  | 7.73 (± 9.607)  |  |  |
| Pain Interference           | -3.98 (± 7.889) | -9.56 (± 8.668) |  |  |
| Pain Intensity              | -1.7 (± 3.00)   | -3.3 (± 3.01)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved at Least a 5-point Improvement From Baseline in Each PROMIS-29 Domain at Week 16

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved at Least a 5-point Improvement From Baseline in Each PROMIS-29 Domain at Week 16 |
|-----------------|--|

End point description:

PROMIS-29, 29-item generic HRQoL survey, assesses each 7 PROMIS domains (depression; anxiety; physical function; pain interference; fatigue; sleep disturbance and ability to participate in social roles and activities) with 4 questions. The questions were ranked on 5-point Likert Scale (1=never, 2=rarely, 3=sometimes, 4=often and 5= always). Pain intensity was rated on 11-point scale (0=no pain; 10=worst imaginable pain). Norm-based scores have been calculated for each domain on PROMIS measures, score of 50 represents mean or average of reference population. Score of 60 means that person is one standard deviation above reference population. On symptom-oriented domains (anxiety, depression, fatigue, pain interference and sleep disturbance), higher scores represent worse symptomatology. On function-oriented domains (physical functioning and social role), higher scores represent better functioning. FAS: all randomised subjects who received at least 1 administration of study intervention.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       |                 |                                       |                                       |  |
| Physical Function             | 11.6            | 23.3                                  | 41.9                                  | 36.6                                   |
| Anxiety                       | 30.2            | 32.6                                  | 44.2                                  | 53.7                                   |
| Depression                    | 23.3            | 27.9                                  | 34.9                                  | 26.8                                   |
| Fatigue                       | 18.6            | 20.9                                  | 23.3                                  | 41.5                                   |
| Sleep Disturbance             | 16.3            | 23.3                                  | 32.6                                  | 43.9                                   |
| Social Roles and Activities   | 23.3            | 30.2                                  | 46.5                                  | 56.1                                   |
| Pain Interference             | 20.9            | 46.5                                  | 55.8                                  | 51.2                                   |

| End point values | JNJ-77242113<br>100 mg QD + | JNJ-77242113<br>100 mg BID + |  |  |
|------------------|-----------------------------|------------------------------|--|--|
|------------------|-----------------------------|------------------------------|--|--|

|                               | Placebo         | Placebo         |  |  |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type            | Reporting group | Reporting group |  |  |
| Number of subjects analysed   | 43              | 42              |  |  |
| Units: Percentage of subjects |                 |                 |  |  |
| number (not applicable)       |                 |                 |  |  |
| Physical Function             | 37.2            | 40.5            |  |  |
| Anxiety                       | 41.9            | 54.8            |  |  |
| Depression                    | 32.6            | 35.7            |  |  |
| Fatigue                       | 25.6            | 42.9            |  |  |
| Sleep Disturbance             | 23.3            | 38.1            |  |  |
| Social Roles and Activities   | 44.2            | 57.1            |  |  |
| Pain Interference             | 41.9            | 64.3            |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects With Treatment-emergent Adverse Event (TEAEs) and Serious TEAEs

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects With Treatment-emergent Adverse Event (TEAEs) and Serious TEAEs |
|-----------------|--|

End point description:

An AE was any untoward medical occurrence in a clinical investigation where subjects administered a product or medical device; the event needed not necessarily have a causal relationship with the treatment or usage. A SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, or resulted in congenital anomaly/birth defect. TEAE was defined as any event that occurs at or after the initial administration of study agent. The safety analyses set included all randomised subjects who received at least 1 administration of study intervention.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From baseline (Week 0) up to 4 weeks after last dose of study drug (up to 20 weeks)

| End point values              | Placebo         | JNJ-77242113<br>25 mg QD +<br>Placebo | JNJ-77242113<br>50 mg QD +<br>Placebo | JNJ-77242113<br>25 mg BID +<br>Placebo |
|-------------------------------|-----------------|---------------------------------------|---------------------------------------|--|
| Subject group type            | Reporting group | Reporting group                       | Reporting group                       | Reporting group                        |
| Number of subjects analysed   | 43              | 43                                    | 43                                    | 41                                     |
| Units: Percentage of subjects |                 |                                       |                                       |  |
| number (not applicable)       |                 |                                       |                                       |  |
| TEAEs                         | 51.2            | 46.5                                  | 60.5                                  | 48.8                                   |
| Serious TEAEs                 | 0               | 0                                     | 2.3                                   | 0                                      |

| End point values | JNJ-77242113<br>100 mg QD +<br>Placebo | JNJ-77242113<br>100 mg BID +<br>Placebo |  |  |
|------------------|--|---|--|--|
|------------------|--|---|--|--|

|                               |                 |                 |  |  |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type            | Reporting group | Reporting group |  |  |
| Number of subjects analysed   | 43              | 42              |  |  |
| Units: Percentage of subjects |                 |                 |  |  |
| number (not applicable)       |                 |                 |  |  |
| TEAEs                         | 44.2            | 61.9            |  |  |
| Serious TEAEs                 | 4.7             | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From baseline (Week 0) up to 4 weeks after last dose of study drug (up to 20 weeks)

Adverse event reporting additional description:

The safety analyses set included all randomised subjects who received at least 1 administration of study intervention.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 25.1 |
|--------------------|------|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | JNJ-77242113 25 mg QD + Placebo |
|-----------------------|---------------------------------|

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | JNJ-77242113 100 mg BID + Placebo |
|-----------------------|-----------------------------------|

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | JNJ-77242113 25 mg BID+ Placebo |
|-----------------------|---------------------------------|

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|                       |                                  |
|-----------------------|----------------------------------|
| Reporting group title | JNJ-77242113 100 mg QD + Placebo |
|-----------------------|----------------------------------|

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | JNJ-77242113 50 mg QD + Placebo |
|-----------------------|---------------------------------|

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2\*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

| <b>Serious adverse events</b>                     | Placebo        | JNJ-77242113 25 mg QD + Placebo | JNJ-77242113 100 mg BID + Placebo |
|---|----------------|---------------------------------|-----------------------------------|
| Total subjects affected by serious adverse events |                |                                 |                                   |
| subjects affected / exposed                       | 0 / 43 (0.00%) | 0 / 43 (0.00%)                  | 0 / 42 (0.00%)                    |
| number of deaths (all causes)                     | 0              | 0                               | 0                                 |
| number of deaths resulting from adverse events    |                |                                 |                                   |
| Psychiatric disorders                             |                |                                 |                                   |
| Suicide Attempt                                   |                |                                 |                                   |
| subjects affected / exposed                       | 0 / 43 (0.00%) | 0 / 43 (0.00%)                  | 0 / 42 (0.00%)                    |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 0                           | 0 / 0                             |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0                           | 0 / 0                             |
| Infections and infestations                       |                |                                 |                                   |
| Covid-19  |                |                                 |                                   |
| subjects affected / exposed                       | 0 / 43 (0.00%) | 0 / 43 (0.00%)                  | 0 / 42 (0.00%)                    |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 0                           | 0 / 0                             |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0                           | 0 / 0                             |
| Infected Cyst                                     |                |                                 |                                   |
| subjects affected / exposed                       | 0 / 43 (0.00%) | 0 / 43 (0.00%)                  | 0 / 42 (0.00%)                    |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 0                           | 0 / 0                             |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0                           | 0 / 0                             |

| <b>Serious adverse events</b>                     | JNJ-77242113 25 mg BID+ Placebo | JNJ-77242113 100 mg QD + Placebo | JNJ-77242113 50 mg QD + Placebo |
|---|---------------------------------|----------------------------------|---------------------------------|
| Total subjects affected by serious adverse events |                                 |                                  |                                 |
| subjects affected / exposed                       | 0 / 41 (0.00%)                  | 2 / 43 (4.65%)                   | 1 / 43 (2.33%)                  |
| number of deaths (all causes)                     | 0                               | 0                                | 0                               |
| number of deaths resulting from adverse events    |                                 |                                  |                                 |
| Psychiatric disorders                             |                                 |                                  |                                 |
| Suicide Attempt                                   |                                 |                                  |                                 |
| subjects affected / exposed                       | 0 / 41 (0.00%)                  | 1 / 43 (2.33%)                   | 0 / 43 (0.00%)                  |
| occurrences causally related to treatment / all   | 0 / 0                           | 0 / 1                            | 0 / 0                           |
| deaths causally related to treatment / all        | 0 / 0                           | 0 / 0                            | 0 / 0                           |
| Infections and infestations                       |                                 |                                  |                                 |
| Covid-19  |                                 |                                  |                                 |
| subjects affected / exposed                       | 0 / 41 (0.00%)                  | 1 / 43 (2.33%)                   | 0 / 43 (0.00%)                  |
| occurrences causally related to treatment / all   | 0 / 0                           | 0 / 1                            | 0 / 0                           |
| deaths causally related to treatment / all        | 0 / 0                           | 0 / 0                            | 0 / 0                           |
| Infected Cyst                                     |                                 |                                  |                                 |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

Frequency threshold for reporting non-serious adverse events: 5 %

| <b>Non-serious adverse events</b>                     | Placebo          | JNJ-77242113 25 mg QD + Placebo | JNJ-77242113 100 mg BID + Placebo |
|---|------------------|---------------------------------|-----------------------------------|
| Total subjects affected by non-serious adverse events |                  |                                 |                                   |
| subjects affected / exposed                           | 10 / 43 (23.26%) | 10 / 43 (23.26%)                | 10 / 42 (23.81%)                  |
| Nervous system disorders                              |                  |                                 |                                   |
| Headache  |                  |                                 |                                   |
| subjects affected / exposed                           | 1 / 43 (2.33%)   | 0 / 43 (0.00%)                  | 1 / 42 (2.38%)                    |
| occurrences (all)                                     | 1                | 0                               | 1                                 |
| Gastrointestinal disorders                            |                  |                                 |                                   |
| Diarrhoea   |                  |                                 |                                   |
| subjects affected / exposed                           | 1 / 43 (2.33%)   | 2 / 43 (4.65%)                  | 1 / 42 (2.38%)                    |
| occurrences (all)                                     | 1                | 2                               | 2                                 |
| Respiratory, thoracic and mediastinal disorders       |                  |                                 |                                   |
| Cough   |                  |                                 |                                   |
| subjects affected / exposed                           | 0 / 43 (0.00%)   | 1 / 43 (2.33%)                  | 1 / 42 (2.38%)                    |
| occurrences (all)                                     | 0                | 1                               | 1                                 |
| Infections and infestations                           |                  |                                 |                                   |
| Covid-19  |                  |                                 |                                   |
| subjects affected / exposed                           | 5 / 43 (11.63%)  | 5 / 43 (11.63%)                 | 4 / 42 (9.52%)                    |
| occurrences (all)                                     | 5                | 5                               | 4                                 |
| Nasopharyngitis                                       |                  |                                 |                                   |
| subjects affected / exposed                           | 2 / 43 (4.65%)   | 1 / 43 (2.33%)                  | 2 / 42 (4.76%)                    |
| occurrences (all)                                     | 2                | 1                               | 3                                 |
| Upper Respiratory Tract Infection                     |                  |                                 |                                   |
| subjects affected / exposed                           | 1 / 43 (2.33%)   | 3 / 43 (6.98%)                  | 2 / 42 (4.76%)                    |
| occurrences (all)                                     | 1                | 4                               | 2                                 |

| <b>Non-serious adverse events</b>                     | JNJ-77242113 25 mg BID+ Placebo | JNJ-77242113 100 mg QD + Placebo | JNJ-77242113 50 mg QD + Placebo |
|---|---------------------------------|----------------------------------|---------------------------------|
| Total subjects affected by non-serious adverse events |                                 |                                  |                                 |
| subjects affected / exposed                           | 12 / 41 (29.27%)                | 8 / 43 (18.60%)                  | 15 / 43 (34.88%)                |
| Nervous system disorders                              |                                 |                                  |                                 |

|  |                      |                     |                      |
|--|----------------------|---------------------|----------------------|
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 1 / 41 (2.44%)<br>2  | 3 / 43 (6.98%)<br>3 | 1 / 43 (2.33%)<br>1  |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                  | 2 / 41 (4.88%)<br>2  | 1 / 43 (2.33%)<br>1 | 4 / 43 (9.30%)<br>4  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all) | 0 / 41 (0.00%)<br>0  | 3 / 43 (6.98%)<br>3 | 1 / 43 (2.33%)<br>1  |
| Infections and infestations<br>Covid-19<br>subjects affected / exposed<br>occurrences (all)                  | 8 / 41 (19.51%)<br>8 | 2 / 43 (4.65%)<br>2 | 3 / 43 (6.98%)<br>3  |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)  | 3 / 41 (7.32%)<br>3  | 1 / 43 (2.33%)<br>1 | 8 / 43 (18.60%)<br>9 |
| Upper Respiratory Tract Infection<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 41 (0.00%)<br>0  | 0 / 43 (0.00%)<br>0 | 0 / 43 (0.00%)<br>0  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment  |
|------------------|--|
| 17 November 2021 | The overall reason for the amendment was to clarify stratification and to clarify the contraceptive appendix.  |
| 12 January 2022  | The overall reason for the amendment was to update the study intervention dosing instructions and to update the analysis strategy regarding discontinuations due to COVID-19 (intercurrent event number 3) to a Treatment Policy strategy. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported